DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2005

Mr. Michael M. Kochian
Management Representative,
Quality Assurance and Regulatory Affairs
3TP Imaging Sciences
245 Main Street, Suite #620
WHITE PLAINS NY 10601

Re: K050862
Trade/Device Name: Workspace
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 22, 2005
Received: June 27, 2005

Dear Mr. Kochian:

This letter corrects our substantially equivalent letter of July 25, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**ATTACHMENT 7**

Indications for Use Statement

510(k) Number (if known): K050862

Device Name: Workspace

Indications for Use:

The Workspace is intended for use in conjunction with 3TP's proprietary post processing pharmacokinetic analysis software (FDA 510(k) number: K03150) to provide additional mathematical and/or statistical information specific to a particular region within a 3TP color-coded image. The Workspace does not change the original 3TP Software algorithm or the image series produced by the 3TP algorithm. The Workspace supports the analysis and presentation of datasets generated by 3TP Software algorithm and incorporates the following functions: Pixel of Interest curve (POI), Region of Interest curve (ROI), Report Card, Volume Calculation, 3TP Histogram, and 3-D visualization of 3TP data series.

The POI and ROI curve functions provide contrast enhancement data for a specific pixel or region of interest within the MRI image series. Whereas the POI function measures signal intensity enhancement for a specific pixel, the ROI function *averages* the enhancement in signal intensity for a manually specified region (several pixels). In both cases, the Workspace presents a graph depicting the percent change in intensity through all time points.

The Report Card function classifies, counts and calculates the percentage of pixels of a given color and intensity in a single or in multiple slices for any manually specified region of interest. The Report Card offers the user the ability to evaluate a subset of the data originally generated by the 3TP algorithm in a numbers based, non-image presentation format. The Report Card assists the user by providing number based data of the contrast kinetics of a specified region identified by the radiologist in order to further aid in his diagnosis.

The Volume Calculation function allows the user to measure the volume of a region in multiple image slices specified by the radiologist.

The "3TP Histogram" is used to simultaneously display measurements of two physiological parameters found from a full pharmacokinetic analysis of the dynamic behavior of voxels in a chosen ROI. Each bin in the histogram shows the total number of voxels from the designated ROI with corresponding Permeability (PERM) and Extracellular Volume Fraction (EVF). Two solid lines on the histogram plot show the Blue/Green and Green/Red separations of the map: That is, voxels in the bins of red section are colored red on 3TP-color maps based on full analysis.

The Heterogeneity Analysis provides a standardized statistical analysis of the varying populations of color hue and color intensity within a specified region or volume of interest. This function assists the radiologist in determining the degree of heterogeneity or homogeneity of a user specified region in terms of the color-coded pixels that are contained within. If the Full Analysis was performed, Heterogeneity Analysis may be performed also for Permeability and EVF of voxels within specified ROI.

The Workspace product serves as a workflow roadmap tool that organizes and guides the radiologist through the series of sequential tasks that must be performed in order to arrive at a diagnosis. The specific configuration of product features drives the Workspace's underlying workflow solution for lesion characterization and reporting. This inherent workflow regime integrates easily into the radiologist's existing departmental workflow and can be adapted to fit the needs of each user, thereby streamlining diagnosis.

The 3-D Visualization tool provides colored Maximum Intensity Projections (MIP) or other 3D visualization tools that are specific to the 3TP image datasets.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _√_ OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050862

K050862

ATTACHMENT 7

## Summary of Information Respecting Safety And Effectiveness

JUL 25 2005

This 510(K) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).


Contact: Vincent J. McGill
Phone: (212) 779-9910
Fax; (212) 779-9928


Product: 3TP Workspace
Imaging Processing Software for MR Devices
Manufactured by: 3TP LLC
Distributed by: 3TP LLC

### 1) Indications for Use

The 3TP Workspace is intended for use in conjunction with 3TP's proprietary post processing pharmacokinetic analysis software (FDA 510(k) number: K03150) to provide additional mathematical and/or statistical information specific to a particular region within a 3TP color-coded image. The 3TP Workspace does not change the original 3TP Software algorithm or the image series produced by the 3TP algorithm. The 3TP Workspace supports the analysis and presentation of datasets generated by 3TP Software algorithm and incorporates the following functions: Region of Interest curve (ROI), Pixel of Interest curve (POI), Report Card, Volume Calculation, Statistical Analysis, and 3-D visualization of 3TP data series.

The POI and ROI curve functions provide contrast enhancement data for a specific pixel or region of interest within the MRI image series. Whereas the POI function measures signal intensity enhancement for a specific pixel, the ROI function *averages* the enhancement in signal intensity for a manually specified region (several pixels). In both cases, the 3TP Workspace presents a graph depicting the percent change in intensity through all time points.

The Report Card function classifies, counts and calculates the percentage of pixels of a given color and intensity in a single or in multiple slices for any manually specified region of interest. The Report Card offers the user the ability to evaluate a subset of the data originally generated by the 3TP algorithm in a numbers based, non-image presentation format. The Report Card assists the user by providing number based data of the contrast kinetics of a specified region identified by the radiologist in order to further aid in his diagnosis.

The Volume Calculation function provides the user to measure the volume of a region in multiple image slices specified by the radiologist.

The Statistical Analysis provides a standardized statistical analysis of the varying populations of color hue and color intensity within a specified region or volume of interest. This function assists the radiologist in determining the degree of

heterogeneity or homogeneity of a user specified region in terms of the color-coded pixels that are contained within.

The 3-D Visualization tool provides colored Maximum Intensity Projections (MIP) or other 3D visualization tools that are specific to the 3TP image datasets.

2) **Device Description**

3TP Workspace is intended to be used as post processing software designed to receive 3TP specific series and provide additional tools to analyze those 3TP series. 3TP itself, supports the evaluation of dynamic MR data gathered during the injection of a bolus of contrast media. The resulting time course information can be displayed in a variety of formats, including a parametric image overlaid onto source MR images.

3) **Marketing History**

The software has not yet been marketed.

4) **Predicate Devices**

| | | |
|---|---|---|
| GE Advantage Windows With Functool Option (K960265) GE Medical Systems 300 N. Grandview Blvd. Waukesha, WI 53186 | GE Prostate Spectroscopy and Imaging Exam (PROSE) (K011604) GE Medical Systems 300 N. Grandview Blvd. Waukesha, WI 53186 | Philips EasyVision (Quantitative Analysis Option) (K971965) Philips Medical Systems 575 East Sunset Way Issaquah, WA 98027 |

Similar to each of the named predicate devices the 3TP Workspace provides a post-processing means for analyzing changes in signal intensity of a contrast agent as reflected in MR images. The use of the 3TP Workspace does not result in any additional hazards, compared to the other post-processing software packages (Functool, PROSE and Philips EasyVision) currently being marketed by GE Medical Systems, and Philips Medical Systems. The 3TP Workspace does not include any new indications for use nor does the use of this device result in any new potential hazards.

5. **Performance Testing**

The 3TP Workspace will successfully complete integration testing and verification prior to beta validation and the software beta testing will be successfully completed validating the 3TP Workspace prior to market release.